

**Summary Minutes of the Science Advisory Board Metals Risk Assessment
Framework Review Panel Public Teleconference
January 26, 2005, 11:00 a.m. – 2:00 p.m. EST**

Panel Members: See Panel Roster – Appendix A

Date and Time: Wednesday, January 26, 2005, 11:00 a.m – 2:00 p.m. Eastern Time

Purpose: The purpose of this teleconference meeting of the Science Advisory Board (SAB) Metals Risk Assessment Framework Review Panel was to prepare for a face-to-face review meeting by: 1) discussing the draft Framework for Inorganic Metals Risk Assessment and the charge questions to the Panel, and 2) discussing the agenda and Panel assignments for the face-to-face meeting.

Attendees: Chair: Dr. Deborah Swackhamer

Panel Members:

- Dr. Max Costa
- Dr. David Dzomak
- Dr. Kevin Farley
- Dr. Ivan Fernandez
- Dr. Bruce Fowler
- Dr. Andrew J. Friedland
- Dr. A. Jay Gandolfi
- Dr. Joshua Hamilton
- Dr. Kim Hayes
- Dr. Robert Hudson
- Dr. Thomas La Point
- Dr. Samuel Luoma
- Dr. Glenn Miller
- Dr. James Shine
- Dr. Katherine Squibb
- Dr. William Stubblefield
- Dr. Bernard Weiss
- Dr. John Westall
- Dr. Herbert Windom
- Dr. Judith Zelikoff

EPA SAB Staff: Dr. Thomas Armitage, Designated Federal Officer
Dr. Anthony Maciorowski, Associate Director
EPA Science Advisory Board Staff Office

Other EPA Staff: Dr. Anne Fairbrother, EPA National Health and
Environmental Effects Research Laboratory
Mr. Keith Matthews, EPA Office of General
Counsel

Dr. Pamela Noyes, EPA National Center for
Environmental Assessment
Dr. Keith Sappington, EPA National Center for
Environmental Assessment
Dr. Randall Wentzel, EPA Office of Water
Dr. William Wood, EPA National Center for
Environmental Assessment

Others Participating:

Kevin Bromberg, U.S. Small Business
Administration
Larry Kaputska, Ecological Planning and
Toxicology, Inc.
James Laity, Office of Management and Budget
Debra Littleton, U.S. Department of Energy
Jane Luxton, King and Spalding, LLP
Margaret MacDonell, Argonne National Laboratory
Ann Smith Reiser, Asincorp.
Laura Solem, Minnesota Pollution Control Agency

Meeting Summary

The discussion followed the issues and timing as presented in the meeting agenda (Appendix B)

Convene Meeting, Call Attendance

Dr. Thomas Armitage, Designated Federal Officer (DFO) for the SAB Metals Risk Assessment Review Panel called attendance. He noted that the teleconference was being held as a public meeting under the requirements of the Federal Advisory Committee Act (FACA). The DFO is present at all such meetings to assure compliance with FACA requirements. Meeting minutes were taken by the DFO for the teleconference. Dr. Armitage noted that the minutes would be certified by the Panel Chair and made available on the SAB website. He also noted that all Panel members had submitted financial conflict of interest information that was reviewed by the SAB Staff Office prior to the teleconference. Review of the information indicated that there were no conflicts of interest or appearances of lack of impartiality.

Dr. Anthony Maciorowski, SAB Staff Office Associate Director for Science thanked the panel for their efforts. He noted that the Panel would be providing important advice to EPA to ensure the quality of science.

Purpose of the Call and Review of the Agenda

Dr. Deborah Swackhamer, Panel Chair thanked the Panel members for serving and reviewed the agenda for the teleconference. She stated that the purpose of the teleconference was to prepare for the face-to-face Panel meeting to be held on February 3-5 in Washington, D.C. She stated that the teleconference would provide an opportunity for the Panel to discuss EPA's charge to the Panel, and to ask EPA clarifying questions about the charge questions. She also indicated that the face-to-face meeting agenda and Panel member work assignments would be discussed.

Overview of EPA's Framework for Inorganic Metals Risk Assessment (the Framework)

EPA staff provided an overview of the Agency's Framework for Inorganic Metals Risk Assessment. EPA staff expressed appreciation for the Science Advisory Board's willingness to review the Metals Risk Assessment Framework and indicated that the Agency has previously had a productive exchange with the SAB on development of the Metals Action Plan.

EPA staff provided an overview of the process used to develop the Framework for Inorganic Metals Risk Assessment and described the issue papers that were developed as precursors to the Framework document (EPA Staff presentations are provided in Appendix C below). EPA staff described the purpose of the Framework and indicated that it was not intended to be a textbook. The Framework was developed to describe what is known about metals risk assessment, default assumptions that should be used, and research that is needed to fill the gaps

EPA staff described the chronological development of the Framework. EPA staff noted that the Framework was peer reviewed and that EPA received public comments on the document. The review and public comment activities were described.

Panel members asked a number of questions about document. Panelists asked how Sections 2 and 3 of the document were developed, and who the audience was. EPA responded that those sections were primarily written by a steering committee. The audience was intended to be interested risk assessors.

EPA staff noted that the Framework is not a step-by-step guidance document. The Framework was written to highlight the unique properties of metals and metal compounds that should be considered in the risk assessment process. EPA staff noted that the focus of the Framework is on inorganic metal compounds although a section is included on transformation processes. EPA staff noted that metals mixtures are addressed in the document.

EPA staff briefly described all of the sections of the Framework document and the issues covered in each. Section 1 of the Framework provides information on the purpose of the document, target audiences, and the types of risk assessment (e.g., national and site specific) that are discussed in the document. Section 2 of the Framework addresses problem formulation and metals principles. It discusses issues related to such topics as toxicity testing and bioavailability. A conceptual model is also presented.

Recommendations are presented in Section 3 of the Framework. EPA staff noted that the recommendations in Section 3 of the Framework are linked to text in Section 4 of the document where supporting science is presented. Section 4 of the Framework focuses on specific issues in environmental chemistry, human health exposure pathway analysis, human health effects, ecological exposure pathway analysis, and characterization of ecological effects. Section 5 of the Framework was written to acknowledge that there are research needs in metals risk assessment.

EPA staff discussed the table in the appendix of the Framework document. EPA staff noted that the table was developed as an example of how various risk assessment tools could be associated with different levels of risk assessment (e.g., ranking/categorization, national, and site specific)

Panel members asked a number of questions about the purpose of the document and material provided in various sections. A panelist asked whether there was any focus in the Framework on sources of metals. EPA staff responded that this was not specifically addressed. A panelist asked whether EPA planned to “test” the document by providing it to risk assessors. EPA staff responded that an interim interagency review process had been completed.

Panelists asked a number of questions about the audiences of the Framework and whether the document was intended to be specific guidance for risk assessors or a statement of policy concerning what EPA is looking for in risk assessment. EPA staff stated that, on a broad scale, risk assessments for inorganic metals must be treated differently from organics. EPA staff stated that the document provides information to ensure that these differences are incorporated into Agency activities. The document also discusses tools that can be used in risk assessment for inorganic metals.

A panelist noted that in developing its Metals Action Plan, EPA previously indicated that an effort would be undertaken to look at how metals should be ranked for risk assessment. The panelist asked whether this was still under consideration. EPA responded that this was being considered but that the Agency first wanted to obtain the results of SAB review of the Framework.

The Panel Chair asked whether EPA planned to develop specific guidance documents for metals risk assessment after the Framework is completed. EPA staff responded that the Agency was considering having program offices revise their own guidance on the basis of the Framework document.

Discussion of the Charge to the Panel

Panelists asked EPA a number of questions about the specific charge questions that had been provided by EPA to the Panel.

Panelists noted that EPA asked the Panel to comment on the utility of the document to intended audiences and asked how EPA wanted risk assessors to use the document. EPA

staff responded that the purpose of the document was to point out what is unique about metals risk assessment and what alternative approaches should be considered. Panelists asked the Chair whether, in responding to specific charge questions, there would be an opportunity to make broader statements about the document. The Chair responded that the Panel could provide additional advice. However, the Chair noted that she did not want the Panel to drift too far from the specific requests for comment in the charge questions.

A panelist noted that none of the charge questions could be answered with short responses. The panelist stated that the questions were broad and deep. The Panelist stated that, based upon a previous SAB review of the Metals Action Plan, there was an expectation that EPA would be developing specific risk assessment guidance for metals. He asked why EPA had decided not to develop such specific guidance. EPA responded that the question of whether to develop such guidance was open, and that the Agency would like to first obtain the SAB review of the Framework. Another panelist noted that although the Framework was intended to be a guidance document, it did not contain a chapter on integration of the risk assessment process. He questioned how the Panel could discuss integration of the process in the context of the charge questions. EPA staff responded that the panel could take up this discussion when looking at the “Problem Formulation” section of the Framework (Section 2).

Public Comments

The Chair noted that if there were no further questions concerning the charge public comments would be taken. The Designated Federal Officer stated that he had received requests from two individuals to comment: 1) Dr. William Adams, and 2) Ms. Jane Luxton. Dr. Adams was not present on the teleconference. Ms. Luxton indicated that she did not have specific comments, but she observed that previous discussions had taken place concerning the development of a separate metals risk assessment guidance document and the idea of ranking metals. She asked whether the Panel would consider this topic. EPA staff commented that there had been a diversity of opinion on whether a separate guidance document was needed and noted that the Agency would like to receive comment on the Framework before there is discussion of separate guidance.

Mr. Kevin Bromberg of the Small Business Administration stated that public comments had been received on the draft Framework document and that they had been provided to the Panel for informational purposes. Mr. Bromberg stated that he hoped panel members would read these comments and take them into consideration in their review of the document.

Review of the February 1-3 Meeting Agenda and Panel Assignments

At the conclusion of public comments the Chair reviewed the agenda for the planned face-to-face meeting of the panel on February 1-3. She stated that the Panel had been asked to respond to quite a large number of charge questions. She stated in order to organize the meeting to respond to the charge questions, panelists had been assigned to

three breakout groups. The Chair stated that each of the panelists had been assigned to a breakout group addressing one of the following topics: human health risk assessment, environmental chemistry, or ecological risk assessment. The Chair stated that panelists in each group would respond to assigned charge questions in these areas. The Chair then reviewed the breakout group and charge question assignments. The Chair noted that in order to conduct a successful review of the document, panelists should read it ahead of time and come prepared to discuss their responses to the assigned charge questions. Several panelists noted that it would be important for members of the panel to develop detailed responses to the questions ahead of time. The Chair noted that after the breakout sessions, the entire panel would deliberate on all of the charge question responses. The Chair asked whether there were any additional questions concerning assignments. There were no further questions.

Several public participants asked whether they could attend the individual breakout sessions. The Designated Federal Officer indicated that these sessions would be open to the public. The Chair stated that only the panelists would be participating in the discussion during the breakout sessions, but she asked that EPA staff be present to respond to questions.

Summary of Action Items

The Chair thanked panel members and EPA staff for participating in the teleconference and reviewed the list of the review material and background information that had been provided to the Panel. She again reminded panelists of their homework assignments and indicated that she looked forward to seeing them at the face-to-face meeting. The Chair then adjourned the teleconference.

Respectfully Submitted:

Certified as True:

/Signed/

/Signed/

Thomas M. Armitage, Ph.D.
Designated Federal Officer

Deborah L. Swackhamer, Ph.D.
Panel Chair

APPENDICES

Appendix A: Roster of SAB Metals Risk Assessment Framework Review Panel

Appendix B: Teleconference Agenda

Appendix C: EPA Presentations

APPENDIX A - Panel Roster

U.S. Environmental Protection Agency Science Advisory Board Metals Risk Assessment Framework Review Panel

CHAIR

Dr. Deborah Swackhamer, Professor, School of Public Health, University of Minnesota, Minneapolis, MN

MEMBERS

Dr. Max Costa, Professor and Chairman, Department of Environmental Medicine, New York University School of Medicine, New York, NY

Dr. David Dzombak, Professor, Department of Civil and Environmental Engineering, Carnegie Mellon University, Pittsburgh, PA

Dr. Kevin Farley, Professor, Department of Civil and Environmental Engineering, Manhattan College, Riverdale, NY

Dr. Ivan Fernandez, Professor, Department of Plant, Soil, and Environmental Sciences, University of Maine, Orono, ME

Dr. Bruce Fowler, Assistant Director for Science, Division of Toxicology, Agency for Toxic Substances and Disease Registry, Atlanta, GA

Dr. Andrew J. Friedland, Professor and Chair, Environmental Studies Program, Dartmouth College, Hanover, NH

Dr. A. Jay Gandolfi, Assistant Dean for Research and Graduate Studies, College of Pharmacy, University of Arizona, Tucson, AZ

Dr. Joshua Hamilton, Professor, Department of Pharmacology and Toxicology, Dartmouth Medical School, Hanover, NH

Dr. Kim Hayes, Professor and Director, Environmental and Water Resources Engineering Program, University of Michigan, Ann Arbor, MI

Dr. Robert Hudson, Associate Professor, Department of Natural Resources and Environmental Science, University of Illinois at Urbana-Champaign, Urbana, IL

Dr. Thomas La Point, Professor and Director, Department of Biological Sciences, University of North Texas, Denton, TX

Dr. Samuel Luoma, Senior Research Hydrologist, U.S. Geological Survey, Menlo Park, CA

Dr. Glenn Miller, Director, Center for Environmental Science and Engineering, University of Nevada, Reno, NV

Dr. James Shine, Assistant Professor of Aquatic Chemistry, Department of Environmental Health, School of Public Health, Harvard University, Boston, MA

Dr. Katherine Squibb, Associate Professor, Department of Epidemiology and Preventative Medicine, University of Maryland School of Medicine, Baltimore, MD

Dr. William Stubblefield, Senior Environmental Toxicologist, Parametrix, Inc., Albany, OR

Dr. Bernard Weiss, Professor of Environmental Medicine, University of Rochester Medical Center, Rochester, NY

Dr. John Westall, Professor, Department of Chemistry, Oregon State University, Corvallis, OR

Dr. Herbert Windom, Professor, Skidaway Institute of Oceanography, Savannah, GA

Dr. Judith Zelikoff, Associate Professor, Department of Environmental Medicine, New York University School of Medicine, Tuxedo, NY

SCIENCE ADVISORY BOARD STAFF

Dr. Thomas Armitage, Designated Federal Officer, US EPA Science Advisory Board (1400F), 1200 Pennsylvania Avenue, NW, Washington, DC 20460

APPENDIX B – Meeting Agenda

SCIENCE ADVISORY BOARD
Metals Risk Assessment Framework Review Panel
Public teleconference
January 26, 2005, 11:00a.m. – 2:00 p.m. (Eastern Standard Time)

Agenda

11:00 am	Convene meeting, Roll Call of Meeting Participants	Dr. Thomas Armitage Designated Federal Officer EPA SAB Staff Office
11:15 am	Welcoming Remarks	Dr. Anthony Maciorowski Associate Director EPA SAB Staff Office
11:20 am	Purpose of the Call and Review of Agenda	Dr. Deborah Swackhamer, Chair
11:30 am	Overview of EPA’s Framework for Inorganic Metals Risk Assessment <ul style="list-style-type: none">- Background- Purpose- Scope- Charge questions to the Panel	Dr. William Wood EPA National Center for Environmental Assessment Dr. Randy Wentsel EPA Office of Water Dr. Anne Fairbrother EPA National Health and Environmental Effects Research Laboratory
12:30 pm	Discussion of the Charge Questions	Dr. Deborah Swackhamer, Chair and Panel
1:15 pm	Public Comments	
1:30 pm	Review Agenda and Panel Assignments for the February 1-3 Meeting	Dr. Deborah Swackhamer, Chair and Panel
1:50 pm	Summary of Action Items	Dr. Deborah Swackhamer, Chair and Panel
2:00 pm	Adjourn	

Framework for Inorganic Metals Risk Assessment

Randall Wentzel and Anne Fairbrother
U.S. EPA
Science Advisory Board Review
February 2005

Background

- Interest in the Agency's assessments of metals and metal compounds
 - e.g., events surrounding promulgation of the Toxics Release Inventory (TRI) lead rulemaking
 - Decision to reduce the amount of lead discharged that require reporting under TRI
 - Based decision on assumptions about the “highly bioaccumulative” nature of lead
 - Challenges to the Agency's use of BCF/BAFs
 - e.g., development of the Agency's Waste Minimization Prioritization Tool

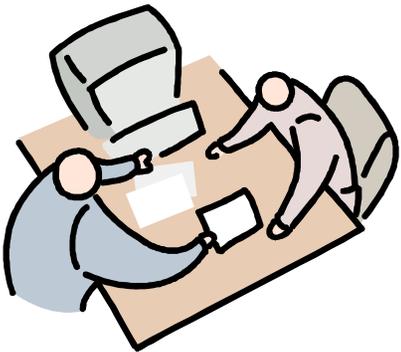
Linda Fisher Charge

- **In establishing a Metals Workgoup, Linda Fisher, former EPA DA, saw that --**

“...a broader, comprehensive evaluation of issues relating to assessment of hazard and risk for other metals and metal compounds related to their PBT characteristics was warranted. Such an assessment would involve reviewing a broad range of physio-chemical properties. These properties may go beyond those encompassed in the PBT framework used in the Lead Rule and may suggest more of a case-by-case (i.e. metal by metal) approach to evaluating other metals and metal compounds.”

Background

- Development of cross-agency guidance for assessing metal and metal compounds should be a priority for EPA
 - Discussions within the Agency, with external stakeholders and with Congress
 - Provide opportunities for external input, peer review and cross-Agency involvement



Phase 1

Metals Action Plan

- ❑ **Metals Action Plan (MAP)**
initiated in 2002
- ❑ **Stakeholder input, February, 2002**
 - **Framework should be developed using sound science**
 - **Environmental chemistry, bioavailability and bioaccumulation are key issues**



Phase 1

Metals Action Plan

- ❑ The MAP recommended a general framework for assessing risks of metals and metals compounds
- ❑ **MAP reviewed by SAB fall 2002**
 - Agreed that metals should be assessed differently from organic chemicals
 - Environmental chemistry, bioavailability, bioaccumulation, and toxicity, among others, were identified as key issues



Phase 2

Metals Issue Papers

- **EPA commissioned external experts to develop papers on metal-specific issues, including**
 - environmental chemistry
 - exposure
 - human health effects
 - ecological effects
 - bioavailability and bioaccumulation



Phase 2

Metals Issue Papers

- ❑ Paper development **led by ERG Inc.**
- ❑ Issue paper authors
 - **28 scientists**
 - From academia, consulting, and Canadian and Federal governments
 - Individual EPA experts contributed specific discussions on topic(s) for which s/he had scientific expertise.
 - **Views expressed are those of the authors**, do not necessarily reflect the views or policies of the EPA, and should not be construed as implying EPA consent or endorsement.



Phase 2

Metals Issue Papers

- **Purpose of Issue Papers:**
 - Capture the **state-of-science** for each metal-specific issue
 - **Identify tools** currently available and under development for metals assessments
 - Provide recommendations for **research needs** to reduce uncertainties

Phase 2

Issue Paper Authors

Environmental Chemistry

- ❑ Donald Langmuir Hydrochem Systems Corp.
- ❑ Paul Chrostowski CPF Associates, Inc.
- ❑ Bernard Vigneault Natural Resources Canada
- ❑ Rufus Chaney U.S. Dept. of Agriculture

Exposure

- ❑ Michael Newman College of Wm. & Mary
- ❑ Gary Diamond Syracuse Research Corp.
- ❑ Charlie Menzie Menzie-Cura & Assoc., Inc.
- ❑ Jacqueline Moya U.S. EPA
- ❑ Jerome Nriagu U. Michigan, Ann Arbor

Ecological Effects

- ❑ Larry Kapustka EP&T
- ❑ William Clements Colorado State U.
- ❑ Linda Ziccardi Exponent
- ❑ Paul Paquin HydroQual, Inc.
- ❑ Mark Sprenger U.S. EPA
- ❑ Daniel Wall U.S. FWS

Phase 2

Issue Paper Authors (cont.)

Human Health Effects

- ❑ **Robert Goyer** **Prof. Emeritus, U. Western Ontario**
- ❑ **Contributors:**
 - **Mari Golub** **U. of California, Davis**
 - **Harlal Choudhury** **U.S. EPA**
 - **Michael Hughes** **U.S. EPA**
 - **Elaina Kenyon** **U.S. EPA**
 - **Marc Stifelman** **U.S. EPA**

Bioavailability & Bioaccumulation

- ❑ **Jim McGeer** **Natural Resources Canada**
- ❑ **Gerry Henningsen** **H&H Scientific Services**
- ❑ **Roman Lanno** **Ohio State U.**
- ❑ **Nicholas Fisher** **State U. at New York, Stony Brook**
- ❑ **Keith Sappington** **U.S. EPA**
- ❑ **John Drexler** **U. of Colorado**
- ❑ **Contributor:**
 - **Michael Beringer** **U.S. EPA**

Phase 2

Focusing Questions for Authors

- What do we know we know?**
- What do we know we don't know?**
- What methods, models, data are available?**
- How should these be used in each of the 3 regulatory contexts?**
- What default assumptions should be used when information is lacking?**
- What research could fill critical information gaps?**

Phase 2

Issue Papers Chronology

- ❑ Dec, 2002: **Workshop** held to initiate activity
- ❑ April, 2003: **Draft papers completed**
- ❑ Sept–Nov, 2003: **Public comment period**
- ❑ Oct 28, 2003: **Stakeholder meeting**
 - Comments generally supportive
 - Stakeholders presented technical papers
- ❑ Aug, 2004: **Final Issue papers completed**
 - Available at –
<http://cfpub2.epa.gov/ncea/cfm/recordisplay.cfm?deid=86119>

Phase 2

Issue Paper Bibliographies

- ❑ **Goyer, RA; Golub, M; Choudhury, H; Hughes, M; Kenyon, E; Stifelman, M. (2004). Issue paper on the human health effects of metals. September 2004.**
- ❑ **Kapustka, LA, Clements, WH; Ziccardi, L; Paquin, PR; Sprenger, M; Wall, D. (2004). Issue paper on the ecological effects of metals. September 2004.**
- ❑ **Langmuir, D; Chrostowsk, P; Vigneault, B; Chaney, R. (2004). Issue paper on the environmental chemistry of metals. September 2004.**
- ❑ **McGeer, J; Henningsen, G; Lanno, R; Fisher, N; Sappington, K; Drexler, JW. (2004). Issue paper on the Bioavailability and Bioaccumulation of Metals. September 2004.**
- ❑ **Newman, MC; Diamond, GL; Menzie, C; Moya, J; Nriagu, J. (2004). Issue paper on metal exposure assessment. September**

Phase 2

Parallel Activities

- July, 2003: Supported and attended **SETAC workshop** on metal assessment
 - Persistence
 - Bioavailability and bioaccumulation
 - Toxicity
- *Unit World Model concept developed*



Phase 3

Metals Framework

- ❑ Feb, 2002 & Oct, 2003: Received public comments on what a Metals Framework should address
- ❑ May, 2004: **Preliminary draft Framework completed**
- ❑ July, 2004: **Peer consultation workshop of preliminary draft Framework**
 - Work groups reviewed the document; provided suggested changes to text and editorial comment
 - Attendees included:
 - Framework steering committee
 - Issue paper lead authors
 - Other external experts
 - EPA Program Offices
 - Other state and Federal government scientists



Phase 3

Metals Framework

- ❑ Sept, 2004: Revised draft for **Intra-Agency review** (internal EPA review)
- ❑ Oct-Nov, 2004: **Inter-Agency review** (review by other federal agencies)
- ❑ Dec 20, 2004: Made available for **public review and comment**
 - Comment period closes Jan 18, 2005
- ❑ Feb, 2005: **SAB review**
 - Public comments will be provided to panel members for informational purposes.

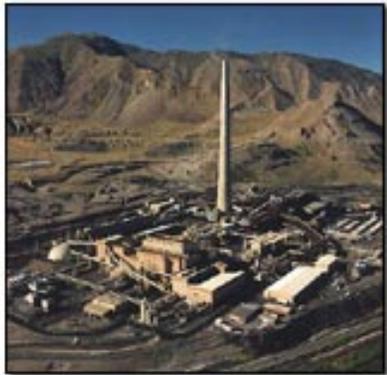
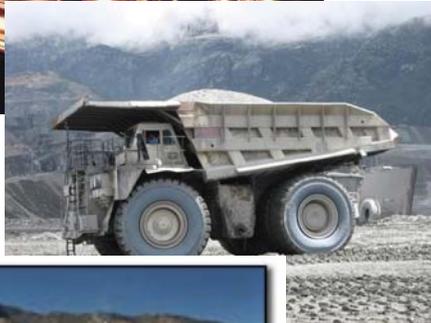
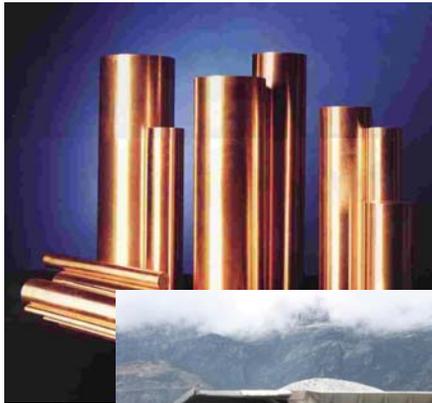


Framework for Inorganic Metals Risk Assessment

Randall Wentzel and Anne Fairbrother
U.S. EPA
Science Advisory Board Review
February 2005

Metals Framework

Charge:



- ❑ **Develop a comprehensive framework that could be the basis of future Agency actions**
- ❑ **Provide a consistent set of basic principles to be considered in assessing risks posed by inorganic metals**
- ❑ **Identify available methods, models, and approaches for use in metals assessments**

Framework Purpose



- ❑ **Science-based document**
 - Addresses the special attributes of inorganic metals and metal compounds when assessing their human health and ecological risks
- ❑ **Provides currently available **tools** and **recommended approaches****
 - Addresses modifications for particular **regulatory contexts**

Framework Purpose (cont.)

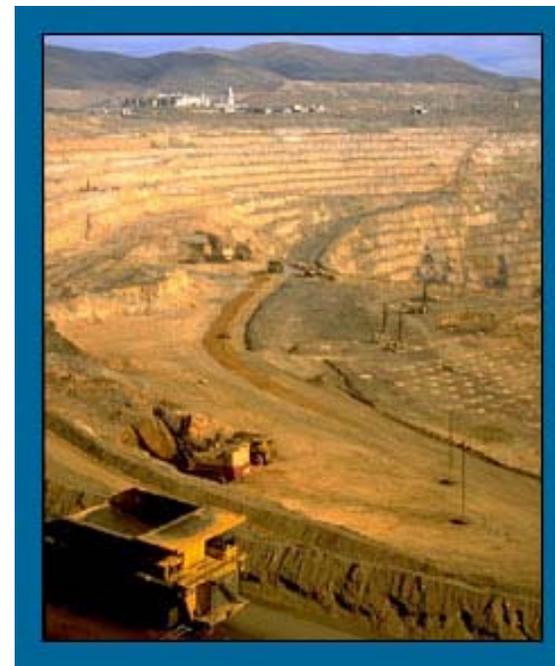


- ❑ Framework **does not** put forward a step by step process
 - Works within current risk assessment guidelines to guide assessors on the **unique properties** of metals and metal compounds
- ❑ Framework **is not** proscriptive for how any particular type of assessment should be done within a USEPA program office

Framework Purpose (cont.)

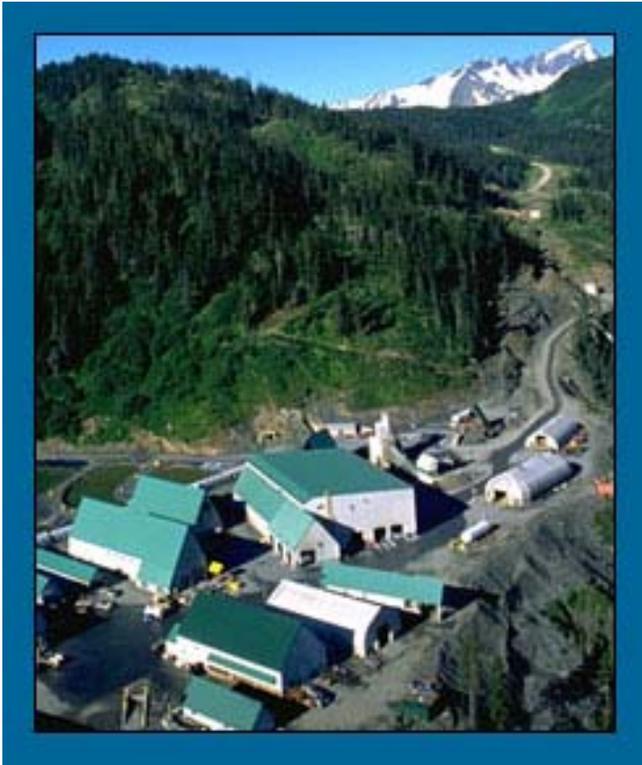
- ❑ Focuses on issues associated with **inorganic metal compounds**
 - However, describes transformation processes for organometallics
 - Methyl mercury not included because other Agency groups are actively addressing issues

- ❑ Meets SAB request to stress importance of **environmental chemistry and mixtures**



Framework Outline

Section 1 - Introduction



- ❑ **Sets out the purpose, scope, and regulatory contexts**
 - **National criteria**
 - **Screening and detailed**
 - **Ranking and Classification**
 - **Site specific assessments**
 - **Screening and detailed**

Framework Section 1

Introduction

- 1.1. Purpose and Audience
 - Guidance to risk assessors on inorganic metals
- 1.2. Framework Scope
 - Science-based on special attributes of inorganic metals
- 1.3. Risk Assessment Framework
- 1.4. Metals Assessment Context
 - National Ranking and Categorization
 - National-Level Assessments
 - Site-Specific Assessments
- 1.5. Organization of Framework

Framework Section 2

Problem Formulation & Metals Principles

To account for **metals-specific differences** in risk analysis –



- ❑ States the **major principles** underlying metals analysis
- ❑ Provides guidance on how to set up the **conceptual model**
- ❑ Provides guidance on the **scope of the assessment**

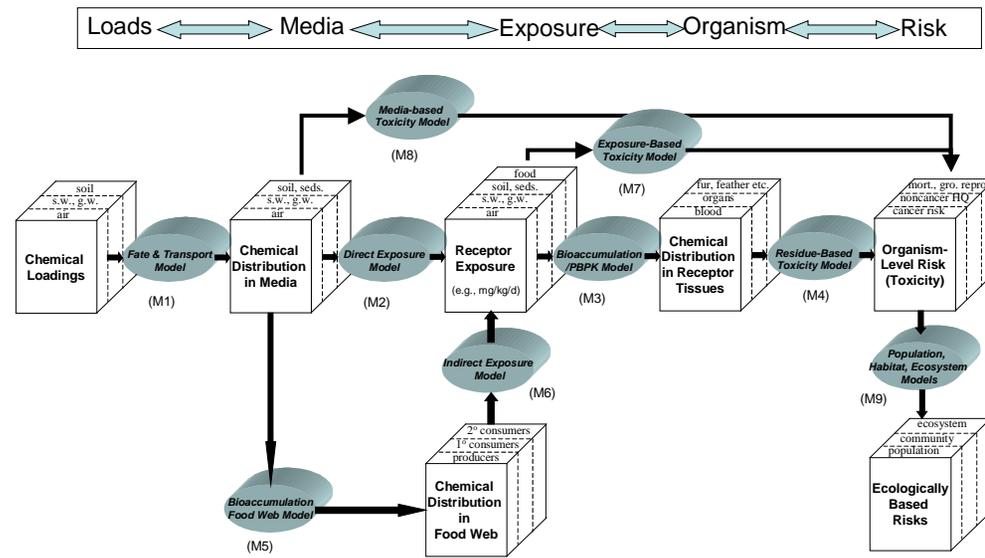
Framework Section 2

Problem Formulation & Metals Principles

- **2.1. Principles of Metals Risk Assessment**
 - ***Identify specific issues which differentiate inorganic metals from other chemicals***
 - Environmental Background Concentrations
 - Essentiality
 - Environmental Chemistry
 - Bioavailability
 - Bioaccumulation and Bioconcentration
 - Acclimation, Adaptation, and Tolerance
 - Toxicity Testing
 - Mixtures

2.2. Metals Conceptual Model

Generic Conceptual Model for Chemical Risk Assessments



Key Metal Issues

(M1). Environmental chemistry (e.g., speciation, trans. kinetics, resusp). Background levels	(M3, M5). Bioavailability, conc. dependency (BAF), essentiality accumulation strategy/regulation, mixture interaction, adaptation	(M7). Bioavailability, env. chem., acclimation metal interact., essentiality, background detox./metabolism
(M2). Environmental chemistry Background levels Concentration dependency	(M4). Intracellular speciation, mode of action, acclimation/adaptation, essentiality, metabolism/excretion	(M8). Bioavailability, env. chem., acclimation metal interact., essentiality, background detox./metabolism
	(M6). Trophic structure, dietary preferences	(M9). Background levels, adaptation, excretion

Framework Section 3

Risk Assessment Recommendations

- ❑ Succinct “**bullet points**” for risk assessors
- ❑ Directed toward **risk assessors** in EPA
 - Program offices, Regional offices
- ❑ Application to various **types of risk assessments**
 - Site-specific, national criteria, ranking or categorization
 - The degree of application will depend on the type and level of the assessment (e.g. screening or detailed)
 - Not all recommendations apply to all types of risk assessments
- ❑ Additional supporting text, etc. in **Section 4** and in the **Issue Papers**

Framework Section 3

Risk Assessment Recommendations

□ 3.1. Human Health

- 3.1.1. Fate and Transport
- 3.1.2. Exposure Assessment: background; air, dietary, water pathways, integrated approaches, bioavailability
- 3.1.3. Effects Analysis: PBPK/PBPD models, essentiality, toxicity, mixtures, sensitive subpopulations/life stages

□ 3.2. Aquatic Environment

- 3.2.1. Fate and Transport
- 3.2.2. Water Column Exposure, Bioavailability, and Effects
- 3.2.3. Background
- 3.2.4. Bioaccumulation
- 3.2.5. Trophic Transfer, Biomagnification, and Dietary Toxicity
- 3.2.6. Sediment Exposure and Effects
- 3.2.7. Metals mixtures

□ 3.2. Terrestrial Environment

- 3.3.1. Fate and Transport: Atmospheric chemistry; soil mobility and transformations
- 3.3.2. Exposure Assessment: Background; soil invertebrates & plants; wildlife; food chain modeling; bioaccumulation;
- 3.3.3. Toxicity Assessment: Adaptation & acclimation; essentiality; metals mixtures; toxicity testing; extrapolation of effects

Framework Section 3

Risk Assessment Recommendations

□ Human Health Examples:

- Exposure from incidental soil or dust ingestion should be adjusted for bioavailability before adding to intake from oral exposure pathways (U.S. EPA, 2004a). See Section 4.2.4 for further discussion
- The IEUBK model for lead in children is recommended for use in all site-specific assessments. It is available on line at ...
- In setting reference values (Reference Concentrations [RfCs]/RfDs) the Recommended Daily Allowance (RDA) should be taken into consideration.

Framework Section 3

Risk Assessment Recommendations

□ Aquatic Environment Examples:

- Most of the available transport models do not currently include chemical speciation subroutines. In such cases, chemical equilibrium models such as MINTEQA2 serve as useful alternatives for characterizing the forms of the metal that are present.
- The BLM offers a mechanistic approach for relating the bioavailability of metals to toxicity. It can be used to develop or revise water quality criteria (e.g., as in the case of copper), in risk assessments, and as an alternative to the WER approaches for setting site-specific discharge objectives.

Framework Section 3

Risk Assessment Recommendations

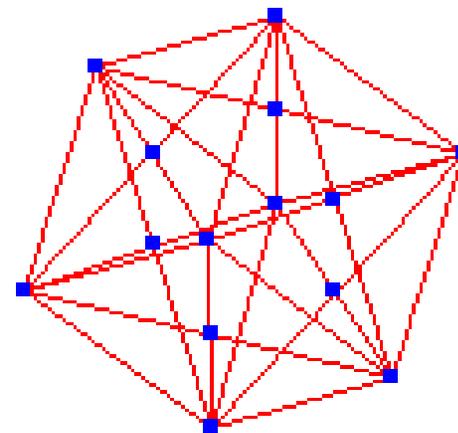
□ Terrestrial Environment Examples:

- Models using partition distribution coefficients (K_d) have significant inaccuracies for metals, and the application of single partition coefficient values for individual metals should be limited to site-specific assessments or to regional- and national-scale studies where bounds of potential K_d values, or reasonably representative single values are adequate.
- For areas of contamination where added metals have aged significantly, reduced bioavailability should be considered. Thus, it becomes important to estimate exposure in terms of the bioavailable fraction.
- Incidental ingestion of soil can be assumed to be an important route for exposure to wildlife when (1) the BAF from soil to food (e.g., to plants or soil invertebrates) is less than 1 and (2) the fraction of soil in the diet is greater than 5%.

Framework Section 4

Metal Specific Topics and Methods

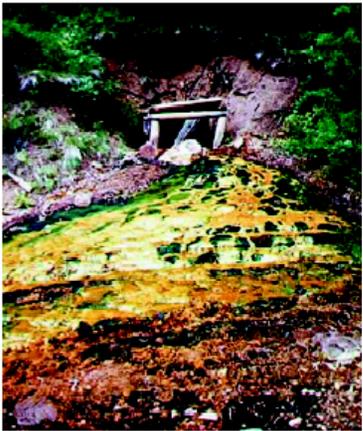
- ❑ **Provide supporting material for Section 3 recommendations**
 - Not meant to be an exhaustive review
- ❑ **Focus is on attributes specific to inorganic metals**
- ❑ **Divided by subject matter (Environmental Chemistry, Human Health and Ecological)**



Framework Section 4

Metal Specific Topics and Methods

- **4.1. ENVIRONMENTAL CHEMISTRY**
 - Reviews Metal Chemistry
 - Discusses Media Specific Chemistry
 - Discusses methods for K_d , aging, soil metal transfer to plants and metal speciation
- **4.2. HUMAN EXPOSURE PATHWAY ANALYSIS**
 - Presents the Applications and Limitations for Models and Methods
 - Discusses Routes of Entry and Integrated Exposure Approaches
 - Reviews Modeling Approaches (e.g. Toxicokinetics and PBPK)
- **4.3. HUMAN HEALTH EFFECTS**
 - Presents Tools and Methods
 - Discusses Essentiality Versus Toxicity
 - Reviews the Toxic and Essential Properties of Metals
 - Reviews Variations in Susceptibility



Framework Section 4

Metal Specific Topics and Methods

- **4.4. ECOLOGICAL EXPOSURE PATHWAY ANALYSIS**
 - Presents Models and Methods
 - Reviews Aquatic and Terrestrial Transport Pathways
 - Discusses Routes of Exposure to Aquatic and Terrestrial Species
- **4.5. CHARACTERIZATION OF ECOLOGICAL EFFECTS**
 - Presents Applications and Limitations of Tools and Methods
 - Reviews Background, Acclimation/ Adaptation, Essentiality, and Mixtures Issues
 - Discusses Bioavailability and BAF/BCF Issues in Terrestrial and Aquatic Systems
 - Reviews Sediment, Soil, and Wildlife Toxicity Issues

Framework Section 5

Research Needs



- ❑ On-going EPA and external research
- ❑ Specific needs for each topic area
- ❑ Discussion of Unit World model
 - Evolving approach for calculating critical loads
 - Currently under development for aquatic compartment
 - Water column & sediment
 - Future work for terrestrial systems

Framework Section 5

Research Needs

- ❑ **5.1. U.S. EPA research**
- ❑ **5.2. External research**
- ❑ **5.3. Specific research recommendations**
 - **Environmental Chemistry**
 - **Bioaccumulation & Bioavailability**
 - **Exposure**
 - **Human Health Effects**
 - **Characterization of Ecological Effects**
- ❑ **Unit World Model for Metals**



Framework Outline

End Sections

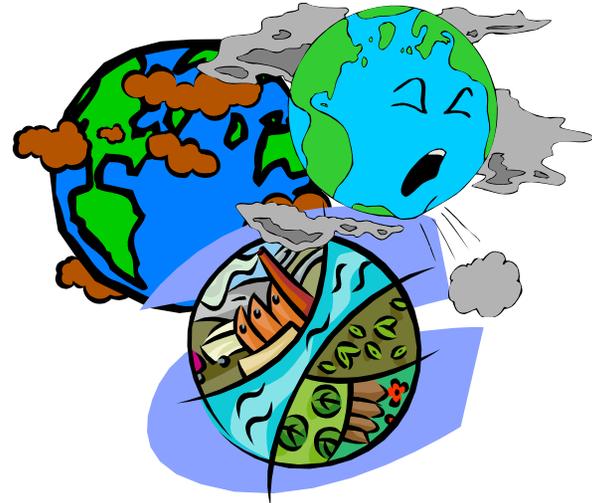
6. GLOSSARY

7. REFERENCES

Sample Appendix

Tables to cross-reference recommendations with risk assessment context

- National criteria
- Ranking and Classification
- Site specific assessments
 - Screening and detailed



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